

REMARKS

The Office Action mailed November 1, 2006 has been carefully considered and this paper is responsive thereto. Claims 1-27 are pending in the application.

At page 2 of the Office Action, the Examiner maintained the provisional rejection of claims 1 and 2 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44 and 45 of copending application Serial No. 10/824,688. The Examiner acknowledged Applicants' request to hold until such time as notice of patentable subject matter has been received in the applications.

Applicants again request that this rejection be held until such time as notice of patentable subject matter has been received in the applications. Applicants will file an appropriate terminal disclaimer at that time if necessary.

At pages 3-5 of the Office Action, the Examiner maintained the rejection of claims 1-17, 20, 21 and 23-27 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376) and the separate rejection of claims 18, 19 and 22 over the same reference for the reasons set out in the previous Office Action mailed March 6, 2006. In the present Office Action, the Examiner indicated that Applicants' arguments based on structural differences between kappa-2 carrageenan and kappa and iota carrageenans disclosed in Gennadios are not sufficient to overcome the rejections because kappa-2 carrageenan and kappa and iota carrageenans possess common structural characteristics and properties.

Applicants traverse these rejections and request reconsideration thereof based upon the arguments of record, which are incorporated herein by reference, as well as the comments set forth herein.

More specifically, Applicants respectfully maintain that Gennadios does not disclose or suggest the presently claimed delivery system comprising a homogeneous, thermoreversible gel film, wherein the gel film comprises, *inter alia*, kappa-2 carrageenan and an active substance or the presently claimed process for making such delivery system. As detailed in the Response

filed on August 7, 2006, kappa-2 carrageenan has a different structure and different properties than kappa carrageenan (and iota carrageenan).

However, the Examiner appears to rely on Applicants' specification as stating that all carrageenans are structurally and functionally similar without providing any additional support for this position or providing clear guidance as to where in the Applicants' specification (at pages 4-7) such support purportedly exists.

Applicants submit that the present application does not support the position that all carrageenans are structurally and functionally similar. Quite the contrary. The present specification, for example, details the known structural differences between the various carrageenans in the molar ratios of 3:6AG-2S to 3:6AG content (e.g., see the present specification at page 5, first full paragraph) and further notes, for example, that iota and kappa carrageenans are known to be "gelling carrageenans" whereas kappa-2 carrageenan is known to be "weakly gelling" (e.g., see the present specification at page 7, first full paragraph). Furthermore, in the paragraph bridging pages 7-8 of the present specification, Applicants further note in the present specification that it is generally recognized that kappa-2 carrageenan has a lower water gel strength than kappa carrageenan, iota carrageenan and simple physical mixtures of kappa and iota carrageenans. As discussed in Henry J. Witt, "Carrageenan Nature's Most Versatile Hydrocolloid", pages 347-360, 1985 (attached hereto as Exhibit A), unmodified fractions of carrageenan, for example, mu, nu, lambda and theta are non-gelling while kappa carrageenan forms strong gels that are firm, brittle and synerese but iota carrageenan, in contrast, forms strong gels that are flexible, resilient and very dry (see, Witt, at pages 348-349). (Witt was previously submitted in an Information Disclosure Statement.) It is clear from the specification and, for example, Witt, that the ability of carrageenans to form gel films varies significantly depending on the type of carrageenan. Applicants respectfully submit that the present specification does not support the position proffered by the Examiner.

Moreover, in view of the differences in structure and in gelling properties generally believed to exist between kappa-2 carrageenan and both kappa and iota carrageenans, persons skilled in the art would not have found the presently claimed invention, i.e., a delivery system comprising a thermoreversible, homogeneous, gel film comprising kappa-2 carrageenan and an

active substance and methods for the manufacture thereof, obvious in view of the disclosures of Gennadios. Gennadios is directed to film forming compositions useful for soft capsules comprising *kappa carrageenan* and would not suggest to one skilled in the art the desirability of a delivery system comprising a gel film comprising kappa-2 carrageenan.

For example, kappa carrageenan is known to be weakly gelling and, based on traditional water gel strength and textural measurement, kappa-2 carrageenan is known to have a low water gel strength when compared to kappa carrageenan, iota carrageenan or physical mixtures of kappa and iota carrageenan and, therefore, would not be expected to be appropriate for delivery system gel film applications. As the inventors here found, when kappa-2 carrageenan is used in making delivery systems comprising gel films, it demonstrates surprising film strength and mechanical integrity, well beyond expectations based on known molecular structuring with respect to water gels. It also demonstrates full compatibility with traditional film ingredients, such as starch, humectant, etc. This surprising film strength of kappa-2 carrageenan also allows carrageenan molecular weight control in order to better balance process viscosity and required film strength for mechanical processing, such direction resulting in the capability to operate at lower moisture levels in the cast films while maintaining other essential film properties. In summary, there is no disclosure or suggestion in Gennadios that a different type of carrageenan could be substituted for kappa carrageenan, much less a weaker gelling carrageenan such as kappa-2 carrageenan. Kappa-2 carrageenan has a much lower water gel strength than kappa carrageenan, iota carrageenan or physical mixtures of kappa and iota carrageenan. To the surprise of Applicants, however, kappa-2 carrageenan forms surprisingly strong gel films with film strength and mechanical integrity well beyond expectations based on known molecular structuring with respect to water gels. Accordingly, withdrawal of the rejections of claims 1-17, 20, 21 and 23-27, and 18, 19 and 22 as obvious under 35 USC 103 is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

Application No.: 10/824793

Docket No.: 10884-00018-US

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 10884-00018-US. A duplicate copy of this paper is enclosed.

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